IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 08-948 (LDD)
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS APOTEX INC. AND APOTEX CORP.'S FED. R. CIV. P. 12(b)(1) AND (6) MOTION TO DISMISS

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Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") respectfully submit this memorandum of law in support of their FED. R. CIV. P. 12(b)(1) and (6) motion to dismiss the Complaint of Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company and Warner Lambert Company LLC (collectively, "Pfizer").

I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS.

This is a Hatch-Waxman patent litigation concerning the now-surrendered U.S. Patent No. 5,273,995 ("the '995 patent"). Pfizer filed this action on December 17, 2008 despite filing an identical action that same day in Illinois where the action is already proceeding. (D.I. 1, Compl.; D.I. 12-2, Feb. 12, 2009 Decl. of John C. Phillips, Jr., Esq. ("Feb. 12, 2009 Phillips Decl.") at Ex. A, *Pfizer Inc. v. Apotex Inc.*, No. 1:08-cv-07231 (N.D. Ill. Dec. 17, 2008) (compl.)) The parties' stipulated that the time for response to the Complaint is February 12, 2009. (D.I. 7, Stipulation and Order for Extension of Time to Answer or Otherwise Respond to Pls.' Compl., granted on Jan. 12, 2009). On February 12, 2009, Apotex Inc. filed a motion to dismiss for lack of personal jurisdiction. (D.I. 9, Mot. to Dismiss for Lack of Jurisdiction over the Person). Also on February 12, Apotex Inc. and Apotex Corp. filed an alternative motion to transfer the case to the U.S. District Court for the Northern District of Illinois, Eastern Division, where the identical action filed by Pfizer is proceeding. (D.I. 11, Mot. to Transfer Case to U.S. District Ct. for the Northern District of Ill., Eastern Division). On February 26, 2009, the parties stipulated to extend the time for Plaintiffs to respond to both motions. (D.I. 16, Stipulation to Extend Time).

II. SUMMARY OF ARGUMENT.

This is a patent case where Pfizer has alleged infringement by Apotex of U.S. Patent No. 5,273,995 ("the '995 patent"). Pfizer contends that the '995 patent covers the drug atorvastatin, marketed under the brand name Lipitor®. Apotex seeks FDA approval to market a generic

version of the drug. Because Pfizer recently surrendered the '995 patent before the United States Patent and Trademark Office ("USPTO"), the '995 patent is, effectively, dead and unenforceable. Since Pfizer no longer has any existing patent rights to enforce for the '995 patent, the only asserted basis for this action—jurisdictional or otherwise—has vanished, thus requiring dismissal as a matter of law.

In prior litigation, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") invalidated the relevant claim in the '995 patent that Pfizer had previously asserted against other generic drug companies. In a belated attempt to try and correct that problem, Pfizer filed a reissue patent application with the USPTO.[1]

Well-settled statutory and case law mandates that the day a reissue patent issues, the original patent upon which it was based is considered dead, and no longer enforceable. On March 17, 2009, the USPTO reissued the '995 patent as U.S Patent No. RE 40,667 ("the '667 patent").[2] Thus, on that same day, the '995 patent asserted here was automatically surrendered to the USPTO, ceasing to exist for any purpose. The '995 patent's claims effectively died, along with Pfizer's claim for alleged patent infringement. With the demise of the '995 patent, there is no longer any Article III Case or Controversy between the parties for which the Court may exercise subject matter jurisdiction over this action. Since Pfizer's enforcement rights terminated as a matter of law upon the surrender of the '995 patent, Pfizer's Complaint no longer

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[1] Apotex disputes that any of the invalidity problems associated with the '995 patent were lawfully correctable before the USPTO.

[2] Apotex will oppose any effort by Pfizer to assert the '667 patent in this action. If Pfizer believes it has a good faith basis to assert that patent against Apotex, it can attempt to do so in a separate action.

states a claim upon which relief can be granted, thus warranting dismissal of the Complaint in its entirety.

III. STATEMENT OF FACTS.

This action arises under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, which Congress enacted for the express purpose of "get[ting] generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

A. Statutory and Regulatory Framework.

In order to obtain FDA approval to sell a drug that has not been previously approved, a company generally must file a new drug application ("NDA"). *See* 21 U.S.C. § 355(b). An NDA applicant must submit, *inter alia*, the number and expiration date of any patent that claims "the drug" or a method of using the drug for which the applicant submitted the application. 21 U.S.C. § 355(b)(2)(A). FDA publishes this information in the *Approved Drug Products with Therapeutic Equivalence Evaluations* publication, commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii). A company may file an abbreviated new drug application ("ANDA"), as Apotex Inc. has done here, for FDA approval to market a generic version of an NDA drug. An ANDA is "abbreviated" in that it substitutes bioequivalence data for the safety and efficacy studies in an NDA. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). An ANDA also contains a "certification" to each patent that claims the drug or a method of using the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii). An applicant seeking approval to market a generic drug before expiration of a listed patent must submit a "paragraph IV certification" stating that the patent is invalid and/or will not be infringed. *See id.* § 355(j)(2)(A)(vii)(IV). The applicant then notifies the patentee and NDA-holder of the factual and legal bases for that certification. *See id.* § 355(j)(2)(B).

The submission of an ANDA containing a paragraph IV certification constitutes a "technical" act of infringement that creates the subject matter jurisdiction necessary for the courts to resolve any disputes regarding infringement or validity even though the generic drug has not been sold. *See* 35 U.S.C. § 271(e)(2)(A); *Eli Lilly*, 496 U.S. at 678. If the patentee files suit within 45 days of receiving notice from the ANDA filer, FDA approval automatically is stayed—regardless of the suit's merit or lack thereof—until the earlier of 30 months or a judicial determination that the patent is invalid and/or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The patent owner, like Pfizer here, therefore has every incentive to delay resolution of the action, and in turn, the approval of the competing generic drug for as long as possible.[3]

B. The Instant Action.

At issue in this case is the prescription drug atorvastatin, which Pfizer markets under the brand-name Lipitor®. Pfizer has listed several patents in FDA's Orange Book in connection with Lipitor®, including the '995 patent. Apotex Inc. has filed an ANDA seeking FDA approval for atorvastatin calcium tablets. (D.I. 1, Compl. ¶ 13). Apotex Inc.'s ANDA included a paragraph IV certification to, among others, the '995 patent. (*Id.* at ¶¶ 13-14, 30, 33). As required by statute, Apotex Inc. properly notified Pfizer of Apotex Inc.'s Paragraph IV ANDA filing. (*Id.* at

[3] In exchange for this powerful 30-month approval stay, Congress imposed an express statutory duty on all parties to "reasonably cooperate in expediting the action" and empowered the courts, *inter alia*, to shorten the 30-month stay if the brand company breaches this duty. 21 U.S.C. § 355(c)(3)(C); *see also Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 40 (D.D.C. 2000) (explaining that the Hatch-Waxman drafters expected litigation to be concluded during this time). "Obviously, this process is designed to allow for the court to resolve any claim of infringement the original patent owner may have against the ANDA applicant as quickly as possible, and, indeed, the statute requires that, in these actions, 'each of the parties shall reasonably cooperate in expediting the action.'" *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 487 (E.D. Va. 2005) (quoting 21 U.S.C. § 355(c)(3)(C)).

¶¶ 13-14, 30). In response, on December 17, 2008, Pfizer filed this lawsuit alleging infringement of only the '995 patent. (*See* D.I. 1, Compl.).

In 2006, years before Pfizer filed the Complaint in this case, the Federal Circuit invalidated the relevant claim (6) of the '995 patent. *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006). In response, on January 16, 2007, Pfizer went back to the USPTO and put the '995 patent into so-called reissue proceedings, attempting to correct the deficiencies in the patent. (March 17, 2009, Decl. of John C. Phillips, Jr., Esq. ("March 17, 2009 Phillips Decl.") Ex. A, '667 patent at cover; *id.* at Ex. B, Prosecution History of U.S. Patent Application No. 11/653,830 ("the '830 application" or "reissue application"), Jan. 11, 2007 Reissue Application Decl. at 1-2). On March 17, 2009, the USPTO issued the reissue application as the '667 patent. (March 17, 2009 Phillips Decl. Ex. A, '667 patent at cover). At the same time, the original '995 patent was surrendered to the USPTO. 35 U.S.C. §§ 251, 252. As a matter of law, any enforcement rights for that patent held by Pfizer no longer exist.

IV. ARGUMENT.

A. The '995 Patent Died When It Was Surrendered to the USPTO.

The section of the patent statute that governs reissue patents mandates that the day a reissue patent issues, the original patent that the new patent was based upon is immediately surrendered to the USPTO. *See* 35 U.S.C. § 252 ("The surrender of the original patent shall take effect upon the issue of the reissued patent . . . ."). Once the original patent is surrendered to the USPTO, the patent is dead; any enforcement rights are extinguished; and its claims cannot be infringed. *See Seattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 827 (Fed. Cir. 1984) ("An original patent cannot be infringed once a reissue patent has issued, for the original patent is surrendered."); *see also Aspex Eyewear, Inc. v. E'Lite Optik, Inc.*, No. Civ.A.3:98-CV-2996-D, 2002 WL 31875577, at *2 (N.D. Tex. Dec. 20, 2002) (granting E'Lite's motion to

dismiss because Aspex surrendered the only patent-in-suit to the USPTO upon issuance of a reissue patent) (a copy of the *Aspex* decision is attached as Exhibit C to the March 17, 2009 Phillips Decl.). Upon surrender of a patent "[t]he original claims *are dead.*" *Seattle Box*, 731 F.2d at 827 (emphasis added). Therefore, when a reissue patent issues, the reissue patentee loses his enforcement rights grounded in the original patent.

The reissue statute applies to the '995 patent-in-suit here. Specifically, once the '667 patent issued on March 17, 2009, Pfizer surrendered the original '995 patent to the USPTO as a matter of law. *See* 35 U.S.C. § 252 (mandatory surrender). That mandatory surrender means that, for all intents and purposes, the original '995 patent claims are dead, and Pfizer's basis to allege infringement under that patent against Apotex no longer exists.

B. With the demise of the '995 patent, there is no longer any subject matter jurisdiction for Pfizer's claim on the '995 patent.

The Court should dismiss Pfizer's claim for alleged infringement of the '995 patent pursuant to FED. R. CIV. P. 12(b)(1) for lack of subject matter jurisdiction because no Federal Case or Controversy remains. U.S. CONST. art. III, § 2. Pfizer alone bears the burden of establishing subject matter jurisdiction for its claims. *Carpet Group Int'l. v. Oriental Rug Imp. Assoc.*, 227 F.3d 62, 69 (3d Cir. 2000); *see also DaimlerChrysler Corp. v. Cuno,* 547 U.S. 332, 342 n.3 (2006) ("[B]ecause '[w]e presume that federal courts lack jurisdiction unless the contrary appears affirmatively from the record.' the party asserting federal jurisdiction when it is challenged has the burden of establishing it." (quoting *Renne v. Geary*, 501 U.S. 312, 316 (1991)). Pfizer cannot meet that burden here—far from it.

Pfizer's only asserted basis for subject matter jurisdiction over its claim on the '995 patent are "the provisions of Title 28, United States Code, Sections 1331 and 1338." (D.I. 1, Compl. ¶ 17). Section 1338, which governs here, confers federal subject matter jurisdiction only

for actions arising under the *patent* statutes. *See* 28 U.S.C. § 1338. However, it is indisputable that upon the surrender of the '995 patent to the USPTO, the '995 patent ceased to exist, along with any claim on that patent under the patent statutes. *See Seattle Box*, 731 F.2d at 827; *Aspex*, 2002 WL 31875577, at * 2.

Where no patent exists, as here, or where a plaintiff has waived its right to assert the patent against a defendant, courts dismiss infringement claims for lack of subject matter jurisdiction. *See e.g., Belk, Inc. v. Meyer Corp., U.S.*, No. 3:07-CV-168-DCK, 2008 WL 2704792, at *4-5 (W.D.N.C. July 7, 2008) (granting motion to dismiss for lack of subject matter jurisdiction where the plaintiff has disclaimed the patents-in-suit); *Cytologix Corp. v. Ventana Med. Sys., Inc.*, Civ. A. No. 04-11783-RWZ, 2007 WL 3037404, at *9 (D. Mass. Oct. 17, 2007) (granting motion to dismiss for lack of subject matter jurisdiction where the plaintiff's assets, including the patents-in-suit, were sold to another, unrelated, party); *Black & Decker Inc. v. Robert Bosch Tool Corp.*, 371 F. Supp. 2d 965, 968-9 (N.D. Ill. 2005) ("Courts have found that no actual controversy existed regarding patent claims that the patentee did not assert."); *W.L. Gore & Assocs., Inc. v. Oak Materials Group, Inc.*, 424 F. Supp. 700, 701-2 (D. Del. 1976) (ordering dismissal for lack of subject matter jurisdiction where patent claims were disclaimed). Thus, where the plaintiff can no longer assert the claims of a patent, the Court lacks subject matter jurisdiction to sustain a claim for patent infringement.

The situation in *Belk* is particularly apt here. In *Belk*, the plaintiffs brought an action for, *inter alia*, a declaratory judgment of patent non-infringement and invalidity against defendants. *Belk*, 2008 WL 2704792, at *1. The defendants argued that the Court should dismiss the complaint for lack of subject matter jurisdiction "because the patents at issue here have been disclaimed, and thus there is no case or controversy." *Id.* at * 3. The court agreed, holding that

no justiciable Case or Controversy remained in view of the disclaimer. *Id.* at *4. So, too, here. Once the '995 patent was surrendered to the USTO, no further Article III Case or Controversy exists, and thus subject matter jurisdiction is lacking, for any claim under that patent.

C. Given the surrender of the '995 patent, Pfizer's Complaint also fails to state a claim upon which relief can be granted as a matter of law.

Dismissal under FED. R. CIV. P. 12(b)(6) is also appropriate when, as here, the Complaint fails to state a claim as a matter of law. *See Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2003) (citing *Hishon v. King & Spaulding*, 467 U.S. 69, 73 (1984)). In the instant case, the only basis for Pfizer's claim for relief, the '995 patent, no longer exists, thus requiring dismissal as a matter of law under FED. R. CIV. P. 12(b)(6).

The *Aspex* case is squarely on point. There, as here, the plaintiff patent owner surrendered the patent-in-suit to the USPTO upon reissue of that patent. *See Aspex*, 2002 WL 31875577, at *1. Defendant E'Lite moved to dismiss the complaint as a matter of law under Rule 12(b)(6), arguing that the plaintiff was asserting infringement of a patent that had been surrendered to the USPTO and therefore could no longer be enforced. *Id.* The court agreed and granted E'Lite's FED. R. CIV. P. 12(b)(6) motion to dismiss, holding that "Aspex cannot obtain relief in the present suit which is based solely on claims that are dead." *Aspex*, 2002 WL 31875577, at *2.

Just as in *Aspex*, when Pfizer surrendered its patent to the USPTO, the claims of the '995 patent died. Enforcement rights for the '995 patent thus no longer exist and Pfizer is left with no patent to assert. Just as the Court in *Aspex* found, dismissal of Pfizer's claim for alleged infringement of the '995 patent is required as a matter of law.

V. CONCLUSION.

When the '995 patent reissued as the '667 patent, the entire '995 patent was surrendered to the USPTO and the claims of that patent died, along with the only basis for Pfizer's Complaint here. With no legally enforceable patent, the Court lacks subject matter jurisdiction over Pfizer's claim for alleged infringement of the '995 patent. And with no existing patent rights to assert, Pfizer cannot state a claim for patent infringement now or in the future under that patent. The Court, therefore, should dismiss Pfizer's Complaint for alleged infringement of the '995 patent in its entirety pursuant to FED. R. CIV. P. 12(b)(1) and (6).

Dated: March 17, 2009

Respectfully submitted,

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